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| 10/817,545 | 04/02/2004 | William Jackson Devlin SR. | DCS-9166 | 2540 |
| 34500 7550 06/25/2008 DADE BEHRING INC. | | EXAMINER | | |
| LEGAL DEPARTMENT | | | AKRAM, IMRAN | |
| 1717 DEERFIELD ROAD DEERFIELD, IL 60015 | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/817.545 DEVLIN, WILLIAM JACKSON Office Action Summary Examiner Art Unit IMRAN AKRAM 1795 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 21 March 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-10 is/are pending in the application. 4a) Of the above claim(s) 6-10 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-5 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (FTO/S5/08)
Paper No(s)/Mail Date _______.

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5 Notice of Informal Patent Application

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DETAILED ACTION

Response to Arguments

 Applicant's arguments filed 3/21/08 have been fully considered but they are not persuasive.

- 2. A primary argument for the allowance of claims 1-4 over Bell lies with the word "server." Applicant asserts that Bell discloses only 1 server. The applicant has defined the word in the specification to mean a combination of shuttle, storage area, and tray (paragraph 26 of applicant's specification). The word is thus given patentable weight corresponding to this definition. As reiterated in the rejections below, Bell discloses the use of two servers as defined by the applicant's specification, not the applicant's arguments. Examiner then respectfully disagrees that with the conjecture that "since only the single reactant carousel 26 is needed" in Bell, "Bell's analyzer would be nonfunctional" (page 4 of arguments). The servers of Bell maintain their functionality because they can simply be deemed as servers by applicant's specification's definition without changing their method of operation.
- 3. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "within the two servers of a <u>single analyzer</u>") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). "A clinical analyzer" of claim 1 can be reasonably interpreted to mean the entire apparatus of the Devlin reference (as in figure 5).

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4. Regarding the rejection of claim 3 under Devlin, Applicant states that "the frequency an assay is requested is unrelated to the time required to conduct an assay" (page 6, paragraph 5). Examiner respectfully disagrees. The amount of time to conduct an assay is certainly related the frequency at which an assay is performed as it defines

the frequency with which an assay can be performed.

5. As for applicant's second arguments for claim 3 under Devlin found on page 7 of the Arguments, Examiner agrees that group A is the same for both pattern of assays. However, as shown in column 4, lines 14-41 of Devlin, group B (all) is larger than group C (none) in the first pattern and group C (all) is larger than group B (none) in the second pattern.

Claim Rejections - 35 USC § 102

 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bell (US 5,679,309).
- Regarding claim 1, Bell discloses a method for increasing the throughput of a clinical analyzer adapted to perform a number of different assays using reagents inventoried in at least two servers (combination of 30, 16, and 20 and 46, 28, and 26).

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wherein a first pattern of assays is to be performed in a first time period and a different second pattern of assays is to be performed in a different second time period, the method comprising duplicating reagents required to conduct a number of assays in the first pattern of assays within the at least two servers (column 9, lines 35-67).

- 9. Claims 1, 2, and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Devlin (US 7,101,715 B2).
- 10. Regarding claim 1, Devlin discloses a method for increasing throughput of a clinical analyzer adapted to perform a number of different assays using reagents inventoried in at least two servers (column 3, line 63 to column 4, line 13), wherein a first pattern of assays is to be performed in a different second time period (column 5, line 63 to column 6, line 9), the method comprising duplicating reagents required to conduct a number of assays in the first pattern of assays within at least two servers (column 2, lines 19-30).
- 11. Regarding claim 2, Devlin discloses the first pattern of assays having a larger portion of a first group of assays and a smaller portion of a second group of assays wherein the second patter of assays has a larger portion of said second group of assays and a smaller portion of said first group of assays (column 4, lines 14-41).
- 12. Regarding claim 5, Devlin discloses selecting reagents from whichever of the at least two servers has the shorter backlog of demand with which to perform assays in the first pattern of assays (column 1, lines 46-63).

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Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 14. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - Resolving the level of ordinary skill in the pertinent art.
 - Considering objective evidence present in the application indicating obviousness or nonobviousness.
- Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell as applied to claim 1 above.
- 16. Regarding claim 2, Bell is capable of performing multiple assays using the multiple servers found in Bell. What is not disclosed, however, is whether the first group of assays is larger or smaller than the second group of assays. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include any permutation of first and second group sizes as this choice would be dependent on the type of reagents used and the types of reactions performed.
- 17. Regarding claim 3, Bell discloses the analyzer comprising a rotatable reaction carousel having cuvette ports for supporting said assays, each and every cuvette port being returned to an original starting position in said carousel in a full operational cycle

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time of the carousel, and wherein said first group of assays comprise assays that are completed in less than one half of said operational cycle time (column 9. lines 35-52).

- 18. Regarding claim 4, Bell discloses said second group of assays comprising assays that require more than one half of said operational cycle time to be completed (column 9, lines 53-67).
- Claim 3 and 4 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Devlin (US 7.101.715 B2).
- 20. Regarding claim 3 and 4, Devlin discloses a rotatable reaction carousel 26 having cuvette ports 20 for supporting said assays, and each and every cuvette port being returned to an original position starting in said carousel in a full operational cycle time of the carousel (column 5, line 63 to column 6, line 9). It is inherent in the invention of Devlin that the first or second group of assays would be completed in less than half or more than half of the operational cycle time, respectively, because this would be dependent of the types of reactions and reagents used. Also, it would have been obvious to one having ordinary skill in the art at the time of invention for the operational cycle time of the first group of assays to be any fraction of time as compared to the second group because this would depend on the reagents used and the type of reactions occurring.

Conclusion

 THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IMRAN AKRAM whose telephone number is (571)270-3241. The examiner can normally be reached on 10-7 Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on 571-272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IΑ

/Alexa D. Neckel/ Supervisory Patent Examiner, Art Unit 1795